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14. ABSTRACT

Traumatic brain injury has been coined the signature injury of OIF/OEF, with posttraumatic headache being a cardinal symptom found to be as high as 36% of soldiers with MTBI. Combat-related headaches are undertreated, associated with high sick calls, missed days, negative psychological/mood states, and impair overall quality of life. Comorbid anxiety, depression, PTSD and other psychological, psychosocial, and health stressors portend poorer TBI/headache outcomes, supporting the need for integrative health care. Development, evaluation, and integration of a specialized posttraumatic headache treatment program into a comprehensive TBI rehabilitation effort is critical to restoration of function, health, and quality of life of our soldiers. This project addresses multiple FY09 TBI/PH topic areas by validating an evidence-based, mind-body approach for prevention and treatment of post-TBI headache, stress, and associated psychological health issues in order to restore function, enhance well being, prevent post-TBI headache chronification, develop psychological resilience, and promote long-standing health benefits. The focus of this project is on evaluation of mindfulness based stress reduction as one, potentially critical component of a comprehensive rehabilitative effort for this group of MTBI patients.

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Introduction

Traumatic brain injury (TBI) has been coined the signature injury of OIF/OEF, with posttraumatic headache (PTH) being a cardinal symptom found to be as high as 36% of soldiers with TBI. Combat-related headaches are undertreated, associated with high sick calls, missed days, negative psychological/mood states, and impair overall quality of life. Comorbid anxiety, depression, PTSD and other psychological, psychosocial, and health stressors portend poorer TBI/headache outcomes, supporting the need for integrative health care. Development, evaluation, and integration of a specialized posttraumatic headache treatment program into a comprehensive TBI rehabilitation effort is critical to restoration of function, health, and quality of life of our soldiers. This project addresses multiple FY09 TBI/PH topic areas by validating an evidence-based, mind-body approach for prevention and treatment of post-TBI headache, stress, and associated psychological health issues in order to restore function, enhance well being, prevent post-TBI headache chronification, develop psychological resilience, and promote long-standing health benefits.

Body

The focus of this project is the rigorous evaluation of mindfulness-based stress reduction (MBSR) as one, potentially critical, component of comprehensive rehabilitative efforts for soldiers suffering from PTH, postconcussion symptoms, and psychological health issues.

MBSR is a training and practice program designed to enhance awareness through intentional, nonjudgmental attention to present-moment experience. The mental calmness achieved through mindfulness training develops through the practice of sustaining non-judgmental attention in the present moment with the aim of cultivating stable, non-reactive, present-moment awareness. The widespread use of MBSR in academic medical centers has produced research demonstrating its efficacy as an intervention for a broad spectrum of stress-aggravated psychological and medical illnesses, including depression, anxiety, substance abuse, cancer, and heart disease. Mindfulness interventions are associated with reductions in pain, stress, depression, anxiety, insomnia, and as well as enhancement of perception of internal control, well-being, and quality of life. For civilians with migraines, MBSR has been shown to decrease headache frequency and severity, anxiety, depression, and negative affect as well as to increase pain tolerance and headache-related self-efficacy. In civilians with mild to moderate TBI, mindfulness training has been shown to enhance quality of life.

This is a randomized, three-arm prospective, behavioral intervention study designed to examine the effects of standard pharmacologic headache care, plus adjunctive training in MBSR, in the treatment of chronic posttraumatic headache in soldiers with MTBI. Chronic PTH is defined as frequent posttraumatic headache persisting for 3 months or more, exhibiting a temporal onset in association with head injury. We will also examine the influence of MBSR on PTSD symptoms, depression and psychological health (PH) as well as headache outcomes.

Specific Aim 1. To determine the efficacy of MBSR compared to a Headache/TBI-specific Education Program (Head-EP) in the treatment of symptoms in soldiers with posttraumatic headache. Primary outcomes include headache frequency, headache severity, and headache-related quality of life.

Hypothesis: Compared to soldiers receiving usual headache care plus Head-EP, those receiving usual headache care plus MBSR will demonstrate significant improvement in headache frequency, headache severity, and headache-related quality of life. The improvements in PTH will be specifically related to improved quality of life and reduction in headache frequency, severity, and disability.

Specific Aim 2. To identify relevant secondary MTBI outcomes associated with standard headache care plus adjunctive MBSR. Secondary endpoints include: balance/dizziness, PTSD symptoms, depression, cognitive functions, stress, sleep disturbances, irritability, blurred vision, sensitivity to light/noise, sick days, health status**,** medication use, substance use, and health care utilization.

Hypothesis: Compared to soldiers receiving usual care plus Head-EP, or usual care alone, those receiving usual care plus MBSR will experience improvement in a broad range of postconcussive symptoms, health and well being.

Specific Aim 3. To identify psychological mechanisms through which MBSR may influence headache in soldiers with TBI. We will examine the influence of pain catastrophizing, rumination, and locus of control on primary endpoints (headache frequency, headache severity and headache-related quality of life). Based on the results of preliminary analyses, sub-analyses testing a mediator model will be conducted.

This is a randomized, placebo-controlled, three-armed prospective, behavioral intervention study designed to examine the effects of standard pharmacologic headache care, plus adjunctive training in MBSR, on the frequency and severity of PTH in the military population. Participants with combat-related TBI were recruited from the Traumatic Brain Injury Clinic and Neurorehabilitation Unit at Womack Army Medical Center (WAMC). This mixed within-between design enables a pre-post, within-participant comparison of the efficacy of each treatment arm, as well as between-group comparisons. Analysis will be conducted using "intention to treat" methods. After an initial 4 week baseline phase of standard headache care only, participants were randomized to one of three arms, 40 subjects per group:

Arm 1. Continuation of standard headache care; or
Arm 2. Continuation of standard headache care plus participation in an 8-week MBSR program; or
Arm 3. Continuation of standard headache care plus participation in an 8-week Head-EP.

The design offers reasonably equivalent complementary therapies in terms of time commitment, visit format and intervention procedures for purposes of differentiating between true and perceived placebo effects. This is a multidisciplinary project involving the efforts of headache specialty neurologists, neuropsychologists, experts in mind-body therapies, and traumatic brain injury specialists. This project is a coordinated effort involving the Womack Army Medical Center, University of North Carolina Medical Center, UNC Departments of Physical Medicine and Rehabilitation, Neurology and Sports Medicine, and the Carolina Headache Institute.

Key Research Accomplishments

This project has accomplished many of the major goals. We developed treatment protocols for a PTH military population; created and selected testing protocols; recruited and trained key personnel; developed and implemented treatment protocols; established communication processes between 3 institutions (UNC, WAMC, and CHI); created a research database; maintained regulatory approvals; and successfully enrolled 97 participants. We recently completed data collection and are in the final stages of data entry.

Prior to project launch, we projected enrollment of 120 participants based on patient flow through the Concussion Clinic at Womack Army Medical Center. We contacted 252 potential participants of which 150 were screened, but were unable to meet our goal of 120 participants. This goal was not accomplished due to several factors: multiple competing concussion studies limited access to qualified participants; multiple changes in clinic operations and key personnel (Clinic Director; local PI) which interrupted study progress; and delays in securing a full-time, on-site research coordinator. The time commitment of the interventions (12 weeks; 2 hour weekly evening meetings) also presented as a barrier to enrollment.

Reportable Outcomes

N/A

Conclusion

We have successfully accomplished the majority of the tasks outlined in the SOW. Once data entry is complete, we will proceed to data analyses and interpretation.

References

Not applicable

Appendices

Not applicable